10/772,101

Filed

February 4, 2004

## AMENDMENTS TO THE CLAIMS

1. (Currently amended) A prosthetic <u>cardiac</u> valve assembly for use in replacing a deficient native <u>cardiac</u> valve, the valve assembly comprising:

a <u>prosthetic cardiac</u> valve having a base, a plurality of commissure points, and a plurality of resilient leaflets;

a <u>prosthetic cardiac</u> valve support configured to be collapsible for transluminal delivery and comprising a first and a second portion, said first portion expandable to contact the anatomical <u>cardiac</u> annulus of the native <u>cardiac</u> valve when the <u>cardiac</u> valve assembly is properly positioned, said second portion supporting the base and the commissure points of the valve; and

a radial restraint for controlling a diameter of the second portion, the radial restraint comprising a wire;

wherein the second portion has a smaller diameter than the first portion when the valve support is maximally expanded.

- 2. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 1, wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter.
- 3. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 1, wherein the radial restraint is capable of substantially resisting collapse below a preset diameter.
- 4. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 1, wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter and substantially resisting collapse below a preset diameter.
  - 5. (Canceled)
  - 6. (Canceled)
  - 7. (Canceled)
  - 8. (Canceled)
  - 9. (Canceled)
  - 10. (Canceled)
  - 11. (Canceled)
- 12. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 1, further comprising a drug-eluting component.

10/772,101

**Filed** 

: February 4, 2004

13. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 1, further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment.

- 14. (Currently amended) The <u>cardiac</u> valve assembly of Claim 1, wherein the <u>prosthetic</u> <u>cardiac</u> valve support comprises at least one wire.
- 15. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 14, wherein the prosthetic cardiac valve support comprises a single length of wire.
- 16. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 15, wherein at least one portion of the single length of wire has a reduced thickness to decrease the radial expansion force.

## Claims 17-30 (Canceled)

- 31. (Currently amended) A prosthetic <u>cardiac</u> valve assembly configured for endoluminal delivery to replace a deficient native <u>cardiac</u> valve, the <u>prosthetic cardiac</u> valve assembly comprising an axial <u>cardiac</u> valve support portion configured to support a prosthetic <u>cardiac</u> valve having at least one leaflet and to prevent substantial interference with the positioning and/or operation of the prosthetic <u>cardiac</u> valve by any residual components of the native <u>cardiac</u> valve, including calcified native <u>cardiac</u> valve components, said support portion comprising at least one radial restraint at a first section of said support portion to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic <u>cardiac</u> valve leaflets and to prevent significant <u>prosthetic cardiac valve</u> regurgitation, and a second section configured to expand in situ for pushing the residual native <u>cardiac valve</u> components against the native <u>cardiac annulus</u> and surrounding tissue, wherein the second section is configured to expand to an expansion diameter different from <u>an expansion diameter that</u>-of the first section.
- 32. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 31, wherein the radial restraint is configured to reduce recoil.
- 33. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 31, wherein the radial restraint comprises a mechanical stop.

## 34. (Canceled)

10/772,101

**Filed** 

: February 4, 2004

35. (Canceled)

36. (Currently amended) The prosthetic cardiac valve assembly of Claim 31, wherein said

second section is configured to be expanded by a balloon catheter.

37. (Currently amended) The prosthetic cardiac valve assembly of Claim 36, wherein said

second section is configured to be expanded beyond its yield point in situ.

38. (Currently amended) The prosthetic cardiac valve assembly of Claim 31, further

comprising a cardiac valvular ring stent configured to expand in situ for pushing against the

residual <u>cardiac</u> native valve components.

:

39. (Currently amended) The prosthetic cardiac valve assembly of Claim 38, wherein the

cardiac valvular ring stent is self-expanding.

40. (Currently amended) The prosthetic cardiac valve assembly of Claim 38, wherein the

cardiac valvular ring stent is configured to be expanded by a balloon catheter.

41. (Currently amended) The prosthetic cardiac valve assembly of Claim 31, further

comprising a stent configured to reduce the recoil of the support portion following self-expansion

of the support portion.

42. (Currently amended) The prosthetic cardiac valve assembly of Claim 38, wherein the

cardiac valvular ring stent is configured to reside within the valve support portion when

deployed.

43. (Currently amended) The prosthetic cardiac valve assembly of Claim 38, wherein the

cardiac valvular ring stent is configured to reside outside the valve support portion when

deployed.

44. (Currently amended) The prosthetic cardiac valve assembly of Claim 31, further

comprising at least one anchor configured to exert sufficient radial forces against the lumen wall

to prevent substantial migration.

45. (Currently amended) The prosthetic cardiac valve assembly of Claim 31, wherein said

radial restraint comprises a wire.

Claims 46-78 (Canceled)

79. (Currently amended) A prosthetic cardiac valve assembly for use in replacing a

deficient native cardiac valve, the valve assembly comprising:

-4-

10/772,101

:

Filed

: February 4, 2004

a <u>cardiac</u> valve having a base, a plurality of commissure points, and a plurality of resilient leaflets;

a <u>cardiac</u> valve support configured to be collapsible for transluminal delivery and comprising a single length of wire, a first portion and a second portion, said first portion expandable to contact the anatomical <u>cardiac</u> annulus of the native <u>cardiac</u> valve when the assembly is properly positioned, said second portion supporting the base and the commissure points of the <u>cardiac</u> valve; and

a radial restraint for controlling a diameter of the second portion;

wherein the single length of wire has a reduced thickness to decrease the radial expansion force.

- 80. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter.
- 81. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint is capable of substantially resisting collapse below a preset diameter.
- 82. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter and substantially resisting collapse below a preset diameter.
- 83. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint comprises a wire.
- 84. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint comprises a thread.
- 85. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint comprises a mechanical stop.
- 86. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint comprises material from which at least a portion of the valve support is made so that the second portion does not expand beyond a preset diameter.
- 87. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 86, wherein the material comprise shape memory material.
- 88. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint comprises a cuff.

10/772,101

Filed

: February 4, 2004

89. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, wherein the radial restraint comprises a stent configured to cooperate with the valve support so as to substantially preclude recoil.

- 90. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, further comprising a drug-eluting component.
- 91. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 79, further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the <u>prosthetic cardiac</u> valve assembly after deployment.
- 92. (Currently amended) A prosthetic <u>cardiac</u> valve assembly configured for endoluminal delivery to replace a deficient native <u>cardiac</u> valve, the <u>prosthetic cardiac</u> valve assembly comprising an axial <u>prosthetic cardiac</u> valve support portion configured to support a prosthetic <u>cardiac</u> valve having at least one leaflet and to prevent substantial interference with the positioning and/or operation of the prosthetic <u>cardiac</u> valve by any residual components of the native <u>cardiac</u> valve, including calcified native <u>cardiac</u> valve components, said <u>prosthetic cardiac</u> support portion comprising at least one radial restraint at a first section of said <u>prosthetic cardiac</u> support portion to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic <u>cardiac</u> valve leaflets and to prevent significant <u>prosthetic cardiac</u> regurgitation, and a second section configured to expand in situ for pushing the residual native <u>cardiac</u> valve components against the native <u>cardiac</u> annulus and surrounding tissue, wherein the second section is configured to expand to a diameter different from that of the first section beyond its yield point in situ by a balloon catheter.
- 93. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 92, further comprising a <u>cardiac valvular ring</u> stent configured to expand in situ for pushing against the residual native cardiac valve components.
- 94. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 93, wherein the <u>cardiac valvular ring</u> stent is configured to reside within the <u>prosthetic cardiac</u> valve support portion when deployed.
- 95. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 93, wherein the <u>cardiac valvular ring</u> stent is configured to reside outside the <u>prosthetic cardiac</u> valve support portion when deployed.

10/772,101

Filed

February 4, 2004

96. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 92, further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration.

- 97. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 92, wherein said radial restraint comprises a wire.
- 98. (Currently amended) A prosthetic <u>cardiac</u> valve assembly configured for endoluminal delivery to replace a deficient native <u>cardiac</u> valve, the <u>prosthetic cardiac</u> valve assembly comprising an axial <u>prosthetic cardiac</u> valve support portion configured to support a prosthetic <u>cardiac</u> valve having at least one leaflet and to prevent substantial interference with the positioning and/or operation of the prosthetic <u>cardiac</u> valve by any residual components of the native <u>cardiac</u> valve, including calcified native <u>cardiac</u> components, said <u>prosthetic cardiac</u> support portion comprising at least one radial restraint at a first section of said <u>prosthetic cardiac</u> support portion to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic <u>cardiac</u> valve leaflets and to prevent significant <u>prosthetic cardiac</u> valve regurgitation, wherein said radial restraint comprises a wire.
- 99. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 98, wherein the radial restraint is configured to reduce recoil.
- 100. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 98, wherein the <u>prosthetic cardiac valve</u> support portion further comprises a second section configured to expand in situ for pushing the residual native <u>cardiac</u> valve components against the native <u>cardiac</u> annulus and surrounding tissue.
- 101. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 100, wherein the second section is configured to expand to a diameter different from that of the first section.
- 102. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 100, wherein said second section is configured to be expanded by a balloon catheter.
- 103. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 102, wherein said second section is configured to be expanded beyond its yield point in situ.

10/772,101

**Filed** 

February 4, 2004

104. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 98, further comprising a <u>cardiac valvular ring</u> stent configured to expand in situ for pushing against the residual native <u>cardiac</u> valve components.

- 105. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 104, wherein the <u>cardiac valvular ring</u> stent is self-expanding.
- 106. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 104, wherein the <u>cardiac valvular ring</u> stent is configured to be expanded by a balloon catheter.
- 107. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 98, further comprising a stent configured to reduce the recoil of the support portion following self-expansion of the <u>prosthetic cardiac valve</u> support portion.
- 108. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 104, wherein the <u>cardiac valvular ring</u> stent is configured to reside within the <u>prosthetic cardiac</u> valve support portion when deployed.
- 109. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 104, wherein the <u>cardiac valvular ring</u> stent is configured to reside outside the <u>prosthetic cardiac</u> valve support portion when deployed.
- 110. (Currently amended) The <u>prosthetic cardiac</u> valve assembly of Claim 98, further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration.